IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC.,)	
Plaintiff and Counterclaim Defendant,)	
v.)	C.A. No. 07-229 (GMS)
)	
RANBAXY INC., and RANBAXY)	
LABORATORIES LIMITED,)	
)	
Defendants and Counterclaim Plaintiffs.)	

MERCK'S OPPOSITION TO RANBAXY'S MOTION (D.I. 63) FOR LEAVE TO FILE A SURREPLY IN OPPOSITION TO MERCK'S MOTION FOR LEAVE TO FILE ITS FIRST SUPPLEMENTAL COMPLAINT

OF COUNSEL:

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Dated: March 12, 2008

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Attorneys for Merck & Co., Inc.

Ranbaxy's motion for leave to file a surreply (D.I. 63) should be denied.

Contrary to Ranbaxy's assertion (*id.* at 1), Merck did not "unfairly save[] material for reply that should have been presented in the Opening Brief." In particular, Ranbaxy seeks a surreply for two reasons: (1) that Merck's Reply cited authority relating to *res judicata* "that should have been presented in its Opening Brief"; and (2) that "Merck waited until its Reply to advance a new theory on the interpretation of ['causes thereafter arising' in 35 U.S.C. § 255] based on language found in the reissue statute [35 U.S.C. § 252]." (*Id.* at 1-2). The points Merck made, however, were in direct response to Ranbaxy's Answering Brief, and Merck had no reason to include them in its Opening Brief. Consequently, Ranbaxy has no basis to file a surreply.

First, Ranbaxy contends that it is entitled to a surreply to address authority Merck included in its Reply showing that res judicata would not bar Merck from filing a subsequent action under the '868 patent with the COC if Merck is not permitted to supplement its

Complaint. But Merck had no reason to address res judicata, and hence to cite authority on res judicata, in its Opening Brief. In order to address the pertinent issues for the Court in its

Opening Brief, Merck wrote to Ranbaxy prior to filing the brief and requested that Ranbaxy provide the basis for its refusal to agree to Merck's proposed supplemental complaint. In responding, Ranbaxy cited only to this Court's decision in ISCO Int'l, Inc. v. Conductus, Inc., 2002 U.S. Dist. LEXIS 21706 (D.Del. Nov. 8, 2002). (Ex. A, Jan. 8 and 9, 2008 letters).

Notably, ISCO says nothing about res judicat; nor do any of the cases ISCO cites, including the Federal Circuit's decision in Southwest Software Inc. v. Harlequin Inc., 226 F.3d 1280 (Fed. Cir. 2000). Indeed, although Ranbaxy's Answering Brief cited seven cases relating to res judicata, not one also addressed the application of a COC. Yet Ranbaxy's Answering Brief contended that the doctrine of res judicata barred Merck from bringing a second action, even for damages,

and that res judicata compelled the conclusion that there is only one cause of action here, which arose prior to the issuance of the COC. (D.I. 51 at 30).

The authority cited in Merck's Reply directly refuted Ranbaxy's new res judicata argument and its new argument regarding a second action for damages. Merck cited cases, such as Alexander & Alexander, Inc. v. Van Impe, establishing that Merck could in fact seek damages in a later action following a declaratory judgment action. 787 F.2d 163, 166 (3rd Cir. 1986) ("The language of the Declaratory Judgment Act itself indicates that a declaration as to the rights and obligations of the parties is not res judicata of a subsequent action for damages."). In reply to Ranbaxy's citation of Section 24(2) of the Restatement (Second) of Judgments (1982), Merck cited Section 33 of the Restatement, which makes clear that a declaratory judgment is conclusive only as to issues that were "actually litigated" by the court in the first action. (D.I. 58 at 7). As a result, as shown in Merck's Reply, if this Court precludes the COC from this lawsuit such that infringement and validity of the '868 patent with the COC are not litigated, res judicata will not bar Merck from bringing a later action once Ranbaxy begins to sell its infringing product. Southwest Software, 226 F.3d at 1297 (any invalidity of the patent due to lack of the COC "ceased" on the date the COC issued). Merck did not improperly "reserve" these authorities for reply as it had no reason to expect res judicata to be an issue. Ranbaxy's request for a surreply is simply an attempt to reargue its res judicata theory and should be rejected.

Second, Ranbaxy asks to file a surreply because Merck argued in its Reply Brief that the language in § 255 that a COC "shall have the same effect and operation in law, on the trial of actions for causes thereafter arising" and should be interpreted consistently with courts' interpretation of the same language in § 252, concerning reissue patents. But again, Merck made this argument in direct reply to an argument in Ranbaxy's Answering Brief, and there was no

reason for Merck to have made this argument in its Opening Brief. Specifically, in its Answering Brief, Ranbaxy argued for the first time a "single cause of action" theory, i.e. that "trial of actions for causes thereafter arising" in § 255 relating to the application of COCs should be interpreted to mean that multiple acts of patent infringement give rise to just a "single cause of action for patent infringement." (D.I. 51 at 22). Merck's reply pointed out that Federal Circuit caselaw interpreting that same statutory language in § 252 "shows that Ranbaxy's contention that a single cause of action exists for a series of infringing acts is simply wrong." (D.I. 58 at 14). As Merck explained, the Federal Circuit's decision in Seattle Box Co. v. Indus. Crating & Packing, Inc, 731 F.2d 818 (Fed. Cir. 1984), interpreting the language in § 252, analyzed infringement under different criteria depending on whether the acts occurred before or after the reissue patent issued. Thus, the Federal Circuit indicated that the multiple acts of infringement gave rise to at least two causes of action.

Merck had no reason to anticipate Ranbaxy's "single cause of action" theory, which Ranbaxy did not mention prior to Merck's Opening Brief (see Ex. A). Indeed, Federal Circuit law is clear that multiple acts of infringement give rise to "multiple causes of action." Hazelquist v. Guchi Moochie Tackle Co., Inc., 437 F.3d 1178, 1181 (Fed. Cir. 2006). Thus, Merck was not obligated to include its argument based on §252 in its Opening Brief and Ranbaxy has no right to a surreply on this issue.

Moreover, Ranbaxy's proposed surreply itself raises an entirely new theory, namely, that the provision in § 252 providing for "intervening rights should similarly limit liability for infringement based on sales which occur after issuance of a certificate of correction under § 255, even in the absence of Southwest Software." (D.I. 63, Ex. A at 5). Ranbaxy should have included its new theory in its Answering Brief so that Merck could respond in its Reply, as

Ranbaxy's new theory is completely contrary to the Federal Circuit's decision in Superior Fireplace Co. v. Majestic Prods. Co., 270 F.3d 1358 (Fed. Cir. 2001), which recognized that Congress provided for intervening rights in § 252 but not in § 255. The Court established a scheme wherein a COC is invalid if it caused an "unanticipated broadening of a claim." Id. at 1371. The Court adopted this approach precisely because § 255 (unlike § 252) did not provide for intervening rights. *Id.* Further, intervening rights would not apply here in any case because the COC for the '868 patent did not alter the language of the claims. See BIC Leisure Prods., Inc. v. Windsurfing Int'l, Inc., 1 F.3d 1214, 1220 (Fed. Cir. 1993) ("The accused infringer may raise the defense of intervening rights only when none of the infringed claims of the reissue patent were present in the original patent.").

Ranbaxy's new argument simply highlights the error of its "single cause of action" argument. The discussion in Superior Fireplace of the lack of intervening rights in § 255 demonstrates that the Federal Circuit does not treat separate acts of infringement, including future acts of infringement that have not yet occurred, as "a single cause of action." The Court would not have needed even to address whether intervening rights applied if all the acts of infringement constituted a single cause of action that arose prior to the issuance of the COC.

For the foregoing reasons, Merck submits that Ranbaxy's request should be denied. If the Court allows Ranbaxy to file its surreply, however, and if the Court deems it appropriate, Merck asks that the Court also allow Merck to file a three-page reply to elaborate on the points made above rebutting Ranbaxy's new argument relating to intervening rights and to address the other arguments raised in Ranbaxy's surreply.

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Dated: March 12, 2008 1903052

CERTIFICATE OF SERVICE

I hereby certify that on March 12, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

> Frederick L. Cottrell, III, Esquire RICHARDS, LAYTON & FINGER, P.A.

> Kelly E. Farnan, Esquire RICHARDS, LAYTON & FINGER, P.A.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on March 12, 2008 upon the following individuals in the manner indicated:

BY EMAIL AND HAND DELIVERY BY EMAIL

Frederick L. Cottrell, III, Esquire Kelly E. Farnan, Esquire RICHARDS, LAYTON & FINGER, P.A. One Rodney Square 920 North King Street Wilmington, DE 19801

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932280

EXHIBIT A

JENNER & BLOCK

January 8, 2008

VIA E-MAIL

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Re: Merck & Co., Inc. v. Ranbaxy Inc. et al., No. 07-229 (GMS)

Dear Mark,

I have enclosed a copy of a draft of Merck's First Supplemental Complaint adding new Counts III, IV, V, and VI, along with a few additional changes. I have enclosed a red-lined copy of the First Supplemental Complaint identifying the differences between the First Supplemental Complaint and the originally filed Complaint.

Count III seeks a declaratory judgment that products covered by Ranbaxy's first ANDA, filed December 29, 2006, will infringe the '868 patent with Certificate of Correction. Counts IV and V seek declaratory judgments that the products covered by Ranbaxy's Vial Pack ANDA, filed August 3, 2007, and Infusion Bottle Pack ANDA, filed August 31, 2007, respectively, will infringe the '868 patent. Count VI seeks a declaratory judgment that the '868 patent with Certificate of Correction is valid.

Pursuant to Local Rule 7.1.1, please let us know by the close of business tomorrow, January 9, whether Ranbaxy agrees that Merck may serve its First Supplemental Complaint. If Ranbaxy does not agree, please let us know which of Counts III, IV, V, and VI Ranbaxy objects to and provide Ranbaxy's reasons for its objection with respect to each such count.

Very truly yours,

Gregory D. Bonifield

GDB:mbw

Enclosure

cc: Counsel of Record



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January 9, 2008

VIA EMAIL

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Cc: Counsel of record

Re: Merck & Co., Inc. v. Ranbaxy Inc. et al., No. 07-229 (GMS)

Our Ref.: L10594

Dear Greg:

Thank you for your letter of January 8, 2008 enclosing Merck's proposed amended complaint. Ranbaxy will oppose any motion to amend. Each of the proposed new counts appears to relate to the "corrected" patent. The law is clear that a Certificate of Correction is not effective in this case. *See*, e.g., ISCO INTERNATIONAL, INC. v. CONDUCTUS, INC., 2002 U.S. Dist. LEXIS 21706 (D. Del. 2002)(Sleet, J.). For at least this reason, the proposed amendment would be futile.

Very truly yours,

Mark Boland